Research within the scope of the Swiss Federal Act on Research involving Human Beings (Human Research Act): State of 2016/2017

Executive summary of project part 3:
Characteristics of jurisdictional inquiries submitted to cantonal ethics committees July-Dec 2017

Submitted to:

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Background

Since January 2016, submissions of research projects needing ethical approval in Switzerland have been managed through the online portal BASEC (Business Administration System for Ethics Committees). Since July 2017, jurisdictional inquiries to a Swiss Ethics Committee (EC) regarding a research project have consistently been processed via BASEC, as well. Jurisdictional inquiries give researchers the possibility to clarify with ECs whether a research project falls within the scope of the Human Research Act (HRA) or not.

Aim of the study

The present report evaluated the reasons for and underlying research projects of jurisdictional inquiries and determined the main difficulties researchers had in the interpretation of legal provisions and terms of the HRA.

Methods

All submissions filed as jurisdictional inquiries through BASEC between 1 July and 31 December 2017 were included in this evaluation. We extracted all relevant information into an iteratively developed, standardised form. In addition, we conducted a survey among researchers who had filed a submission as jurisdictional inquiry to evaluate the submission process from the researcher's perspective.

Results and interpretation

There were a total of 296 submissions filed as jurisdictional inquiries. Based on the researcher's question (free-text) to the EC, we found that of the 296 filed submissions, 218 submissions (74%) were in fact requests to clarify whether the project had to be submitted for ethical approval; three submissions (1%) were requests aimed to clarify which ordinance would apply (ordinance on clinical trials or on human research); 50 submissions (17%) were explicit requests for a "Declaration of No Objection", and 25 submissions (8.4%) were other requests, e.g. communication of protocol deviations and excluded from further analysis. This suggests that not all of the submissions filed as jurisdictional inquiries were actually jurisdictional inquiries . This communication channel was obviously used for other purposes, too.

Regarding the study design, research projects described in the submitted jurisdictional inquiries were most frequently observational studies (43%, 117/271). The majority of jurisdictional requests concerned research with persons (66%, 178/271) and approximately one quarter (71/271) concerned studies with previously collected personal data or biological material.

Of the 296 questionnaires sent out, 166 (56%) were completed. The most frequently stated role in the respective research project was (principal) investigator (48%, 80/166). The majority of researchers (63%, 104/166) worked at a university, including a university hospital. The mean number of years working in research among the survey participants was 9.9 years (95% confidence interval, 8.5-11.3 years). The majority of researchers answered (52%, 87/166) that they have submitted 3 or more research projects to an EC in Switzerland since 1 January 2014. Nearly half (78/166) of the researchers mentioned that they had never used anonymised data before, one quarter (43/166) answered that they sometimes used anonymised data and approximately 15% (25/166) indicated that they frequently used anonymised data.

When asked about the perception of the overall submission process through BASEC, approximately 80% of survey participants answered that the process was clear or nearly clear, concise or nearly concise, convenient or nearly convenient, appropriate or nearly appropriate, respectively. About 50% (84/166) of survey participants rated the duration of the submission "as expected" and 36% (61/166) felt that it was even a bit or much shorter than expected. Regarding the fees payable, 65% (102/166) of the researchers rated these fees "as expected",

but approximately 30% (47/166) found them to be higher than expected. Most researchers (57%, 95/166) had contacted the EC once or several times before they submitted the jurisdictional inquiry. Regarding communication quality with the EC, nearly 90% (147/166) of researchers rated it as “good” or “very good”.

Of those inquiries explicitly requesting a “Declaration of No Objection”, 92% (46/50) resulted in the decision by the EC that the HRA did not apply and 4% (2/50) resulted in calls for submission. Of those inquiries of researchers who were uncertain if the HRA applied, 76% (165/218) resulted in the decision by the EC that the HRA did indeed not apply and 18% (39/218) in calls for submission.

Based on the survey, we found that the vast majority (93%, 154/166) of researchers agreed with the answer given by the EC in response to their jurisdictional inquiry and that 88% (147/166) of the underlying projects were started or planned to start.

Regarding the uncertainty of researchers as to whether or not their project was within the scope of the HRA, we found that most researchers were unsure if their project would produce generalisable knowledge (27%, 59/218), followed by uncertainty regarding the concept of using anonymised data (20%, 43/218). This is corroborated by observed inconsistencies among answers given in the form "brief description of the project", which is typically submitted with the jurisdictional inquiry. Of the 271 jurisdictional inquiries, 68 (25%) inquiries contained a total of 95 inconsistent answers to any of the questions. Most difficulties (44%, 42/95) concerned the comprehension of the question “Are the samples/ data irreversibly anonymised?”. A common issue was, that the question was answered with “yes”, although no data pre-existed in anonymised form before the start of the project, but were obviously generated and anonymised during the conduct of the research project by the researcher, or it was evident that a separate coding list was kept. A similar proportion of researchers stated in the survey that they had difficulties with one or several questions of this form (23.5%, 39/166). Whereas based on BASEC, most inconsistency was found among the answers to the questions on anonymised data, the survey suggested that the prevalence of difficulties was similar across questions (all approximately 20%), in case they had difficulties with this form at all. These findings suggest that a substantial proportion of researchers who were experiencing difficulties with the term “anonymised data” seemed not aware of it.

Limitations

The present report was limited to the information available in BASEC and the data collected in the survey among researchers. We did not contact researchers or ECs in case of missing information in BASEC or in the survey.

Conclusions

Approximately three quarters of submissions, which were filed in BASEC as jurisdictional inquiries in the second half of 2017, were actual requests to clarify whether or not the project had to be submitted for ethical approval; nearly 20% explicitly asked for a “Declaration of No Objection”, and only 1% asked about the applicable ordinance. Overall, researchers were content with the submission process for jurisdictional inquiries in BASEC, 93% of researchers agreed with the reply from the EC, and 88% of the underlying projects were started or planned to start. This means that the current inquiry process appears constructive for researchers. However, researchers seem to have difficulties with the interpretation of legal terms of the HRA, which causes uncertainty about its application. The most commonly observed uncertainty was whether the project would produce generalisable knowledge, and further regarding the concept of using anonymised data. More detailed guidance and illustrative examples may be helpful for researchers.